LABEL IN PART: (Vial) "10 cc Sterile Multiple Dose Vial Injection Cyanocobalamin U.S.P. XV Vitamin B_{12} U.S.P. Crystalline 1000 mcg/cc in Isotonic Normal Saline Solution with 1½% of Benzyl Alcohol–Intramuscular Contains no crude cyanocobalamin."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 1 milligram (=1,000 mcg.) of cyanocobalamin (vitamin B_{12}), 8.77 milligrams of sodium chloride, and 0.98 milligram of unidentified dissolved material.

LIBELED: 8–22–56, E. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained, in each cubic centimeter, dissolved material which was not permitted by the standard as an ingredient of *cyanocobalamin injection;* and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of 505(b), and an application filed pursuant to the law was not effective.

DISPOSITION: Medical Chemicals Corp., claimant, filed an answer denying that the article was a new drug or was adulterated as charged in the libel. The Government filed written interrogatories which the claimant answered in part and objected to in part. Thereafter, the parties having stipulated and agreed on the interrogatories to which answers should be made, the court, on 6–10–57, ordered such interrogatories to be answered.

On 3–25–59, the claimant having represented that the value of the article under seizure was negligible, and that the standard for the article set forth in the United States Pharmacopeia had been clarified to include a specific test for solids which test was not part of the U.S.P. monograph at the time of shipment, and, having consented to the entry of a decree without admitting any of the issues of law and fact involved, judgment of condemnation was entered and the article was ordered destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5707. Various drugs. (F.D.C. No. 41867. S. Nos. 14–201/5 P, 14–207/11 P, 14–213/5 P, 14–223 P, 14–226 P, 14–228 P, 14–230 P.)

QUANTITY: 10 btls. of *Triple-Sulfa No. 1 tablets;* 11 btls. of *Quinidine Sulfate capsules;* 5 btls. of *Quinine Sulfate capsules;* 14 btls. of *stilbestrol tablets;* 6 btls. of *sodium salicylate tablets;* 27 btls. of *sulfadiazine tablets;* 5 btls. of *aminophylline tablets;* 7 btls. of *methyltestosterone sublingual tablets;* 27 btls. of *De-em (dextro-amphetamine sulfate) timed capsules;* 6 btls. of *sulfathiazole tablets;* 5 100-tablet vials and 7 1,000-tablet vials of *thyroid tablets;* 7 btls. of *Neo-Histagen tablets;* 6 btls. of *Theophenyllin tablets;* 22 btls. of *Timcaps (dextro-amphetamine sulfate capsules);* 10 tbls. of *#1 (dextro-amphetamine sulfate with amobarbital) capsules;* and 15 btls. of *#2 (dextro-amphetamine sulfate with amobarbital) capsules,* at Detroit, Mich., in possession of Spartan-Rex Chemical Co.

SHIPPED: Between 1–24–57 and 4–9–58, from Philadelphia, Pa., and Norwich, N.Y.

LABEL IN PART: (Btl.) "1000 Tablets S-R Triple-Sulfa No. 1 7.5 Grains," "1000 Capsules S-R Quinidine Sulfate," "1000 Capsules S-R Quinine Sulfate,"

*See also No. 5705.

"1000 Tablets * * * S-R Stilbestrol," "1000 Tablets Sodium Salicylate." "1000 Tablets S-R Sulfadiazine," "1000 Tablets S-R Buff * * * Aminophylline," "1000 Tablets S-R Methyl Testosterone Sublingual," "De-Em Timed Capsules Dextro Amphetamine Sulfate 10 Mgm Dose * * * Donaker Drug Company, Des Moines, Iowa," "100 Sulfathiazole"; (vial) "100 [or 1000] Tablets Thyroid"; (btl.) "100 Tablets Neo-Histagen with S-P Compound," "100 Theophenyllin Tablets," "1000 Capsules TIMCAPS Dextro Amphetamine Sulfate 15 Mgm. * * * Donaker Drug Company, Des Moines, Iowa," "#1" and "#2."

RESULTS OF INVESTIGATION: The articles, with the exception of the 22 btl. lot of *Timcaps* (*dextro-amphetamine sulfate capsules, 15 mgs.*) were repackaged and relabeled by the dealer after their shipment in interstate commerce as described above.

LIBELED: 6-20-58, E. Dist. Mich.

CHARGE: *Triple Sulfa No. 1 tablets, stilbestrol tablets, sulfadiazine tablets, aminophylline tablets, methyltestosterone sublingual tablets, Quinidine Sulfate capsules, Quinine Sulfate capsules, sodium salicylate tablets.* 502(a)—while held for sale, the label statement "1000 Tablets" (or "1000 capsules") was false and misleading as applied to the articles which contained fewer than 1,000 tablets (or capsules) in each bottle; and 502(b)(2)—the articles failed to bear labels containing an accurate statement of the quantity of contents.

Quinine Sulfate capsules. 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug not subject to 503(b)(1) and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

Sodium salicylate tablets. 502(f)(2)—while held for sale, the labeling of the article failed to bear adequate warning against misuse by children since its labeling failed to bear a statement warning that the article should be kept out of reach of children.

De-Em timed capsules (*dextro-amphetamine sulfate*). 502(a)—while held for sale, the label statement "Donaker Drug Company, Des Moines, Iowa" was false and misleading since such firm was not the manufacturer, packer, or distributor of the article; and 502(b)—the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents.

Sulfathiazole tablets and *thyroid tables.* 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use; and 503(b)(4)—the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Neo-Histagen tablets (*with S-P Compound*). 502(e)(2)—while held for sale, the label of the article failed to bear the common or usual name of each active ingredient; and 502(f)(1)—the labeling failed to bear adequate directions for use; and 502(f)(2)—the labeling failed to bear adequate warning that the article should be kept out of reach of children.

Theophenyllin tablets. 502(d)—while held for sale, the article contained a quantity of phenobarbital, a habit-forming derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient.

Timcaps (*dextro-amphetamine sulfate capsules*). 502(a)—while held for sale, the labeling accompanying the article, namely, the labels to be used in repacking the article, contained a false and misleading statement which represented and suggested that the Donaker Drug Company, Des Moines, Iowa, was the manufacturer of the article.

#1 capsules and *#2 capsules*. 502(b)—while held for sale, the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(d)—the articles contained amobarbital, a derivative of barbituric acid, and their labels failed to bear the name and quantity or proportion of such derivative; 502(e)(2)—the labels of the articles failed to bear the common or usual name of each active ingredient; 502(f)(1)—their labeling failed to bear adequate directions for use; and 503(b)(4)—the articles were subject to 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Spartan-Rex Chemical Co. appeared as claimant for the articles of *Triple-sulfa No. 1 tablets*, *Quinidine Sulfate capsules* (7 btls.), *sulfadiazine tablets*, *methyltestosterone sublingual tablets*, *Timcaps* (dextro-amphetamine sulfate capsules, 15 mgs.) (22 btls.); and having consented to the entry of a decree, judgment of condemnation was entered on 2-6-59 against all of the articles under seizure and the court ordered that the articles claimed by Spartan-Rex Chemical Co. be released under bond for relabeling, and that the remainder of the articles under seizure be delivered to a State hospital.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5708. Aspirin tablets. (F.D.C. No. 41700. S. No. 34-029 P.)

QUANTITY: 42 boxes, each containing 12 ctns. of 12 tins each, at Lehighton, Pa.

SHIPPED: 6-28-48, from Memphis, Tenn.

RESULTS OF INVESTIGATION: Examination showed the article to be 5 grain *aspirin tablets* containing 0.55 percent free salicylic acid, whereas, the United States Pharmacopeia permits a maximum of 0.15 percent free salicylic acid per aspirin tablet.

LIBELED: 5-8-58, M. Dist. Pa.

CHARGE: 501(b)—the quality and purity of the article, while held for sale, fell below the standard for *aspirin tablets* set forth in the United States Pharmacopeia since the article contained more than the permitted amount of free salicylic acid; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 502(f)(2)—the labeling of the article failed to bear adequate warnings against misuse by children, in that, in lieu of a dosage statement for children under 3 years of age, it did not bear a statement that for the 3 year and under age group a physician should be consulted for dosage, and its label did not bear a statement warning that the product should be kept out of reach of children.

DISPOSITION: 6-13-58. Default—destruction.

*See also Nos. 5705, 5707.